



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

Population Assessment of Tobacco and Health (PATH) Study (NIDA)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on March 11, 2016, pages 12913 - 12914 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_Submission@omb.eop.gov or by fax to (202) 395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project, contact: Dr. Kevin P. Conway, Deputy Director, Division of Epidemiology, Services, and Prevention Research, NIDA, NIH, 6001 Executive Boulevard, Room 5185, Rockville, MD 20852; or call non-toll-free number (301) 443-8755 or E-mail your request, including your address to: PATHprojectofficer@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Methodological Studies for the Population Assessment of Tobacco and Health (PATH) Study (NIDA), 0925-0675, expiration date 5/31/2016 – REINSTATEMENT WITHOUT CHANGE - NIDA, NIH, in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a request to continue the Population Assessment of Tobacco and Health (PATH) Study's conduct of methodological studies in support of improvements in the Study's approaches for data and biospecimen collection. The PATH Study is a national longitudinal cohort study of tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17; the Study conducts annual or biannual interviews and collects biospecimens from adults and youth to inform FDA's regulatory actions under

the Family Smoking Prevention and Control Act. The methodological studies under this reinstatement will continue to enhance the approaches used by the PATH Study for data and biospecimen collections to obtain high quality and useful data; minimize respondent burden; and achieve and maintain high response, retention, and follow-up rates.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total annualized burden hours are 29,750.

Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
In-person and telephone surveys	Adults	5,000	1	90/60	7,500
	Youth	3,500	1	90/60	5,250
Web and smartphone/mobile phone surveys	Adults	5,000	1	90/60	7,500
	Youth	3,500	1	90/60	5,250
Focus groups and individual in-depth qualitative interviews	Adults	1000	1	2	2,000
	Youth	1000	1	2	2,000
Biospecimen collection	Adults	1,000	1	15/60	250
Total		20,000	20,000		29,750

Dated: May 27, 2016

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Project Clearance Liaison

NIDA, NIH

